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EXAMINER

COUGHLIN, MATTHEW P

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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04/01/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/585,478	Applicant(s) MITSUDERA ET AL.	
	Examiner Matthew P. Coughlin	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, and 16-18 is/are rejected.
- 7) ☒ Claim(s) 2,4-15 and 19-26 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/07/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-26 are pending in the application. Claims 1, 3 and 16-18 are rejected. Claims 2, 4-15 and 19-26 are objected to.

Priority

This application is a 35 U.S.C. 371 National Stage Filing of International Application No. PCT/JP05/00629, filed January 13th, 2005, which claims priority under 35 U.S.C. 119(a-d) to Japanese Application No. 2004-009149, filed January 16th, 2004.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

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Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement(s) filed on July 7th, 2006.

Claim Objections

Hydrogen is misspelled in claim 5. See end of R5 definition.

Optionally is misspelled in claims 4, 5, 6, 15, 19, 20, 21, 22, 23, 24, 25 and 26 in the definitions of R19, R20 and R21.

In the following section of claim 6:

halogen a group represented by C(OR¹⁹)R²⁰R²¹, or hydrogen, R⁶ represents C1-C5 alkyl optionally substituted with one or more halogen,

there should be a space between "hydrogen," and "R⁶". In addition, a space is needed between "halogen," and "or" in the last line of claim 6.

At the end of claims 4, 5, 15 and 19-26, there should be a space between "halogen," and "or hydrogen" in the last line of each claim.

Claim 7-14 (and their dependent claims 19-26) are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 7-14 are objected to as failing to further limit since they depend from claim 6 but claim 6 only covers one value for the heterocyclic group that does not encompass the heterocyclic groups of claims 7-14.

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Claim Rejections - 35 USC § 112 - 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for controlling an arthropod or nematode pest, does not reasonably provide enablement for a method for controlling all types of pest. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is *undue*. These factors include, but are not limited to: breadth of the claims; nature of the invention; state of the prior art; level of one of ordinary skill in the art; level of predictability in the art; amount of direction provided by the inventor; existence of working examples; and quantity of experimentation needed to make or use the invention based on the content of the disclosure. (See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

The above factors, regarding the present invention, are summarized as follows:

- (a) *Breadth of the claims* - The breadth of the claims includes methods of controlling species encompassed by the term "pests". The general term "pests" as understood by a person having ordinary skill in the art is exceedingly broad. For instance, the International Plant Protection Convention (29th Session of the FAO Conference, November

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1997) defines a pest as (Article II):

Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products.

Similarly, Hamilton and Crossley (Pesticide Residues in Food and Drinking Water, John Wiley & Sons, Ltd. 2004, page 2) define a pesticide as covering:

[...] a wide range of substances, including insecticides, acaricides, fungicides, molluscicides, nematocides, rodenticides, and herbicides.

Therefore the instant claims cover methods of controlling various types of pests, which based upon the ordinary definition that would be applied to the term "pest" can include, for instance, weeds, insects, mice, birds, deer, rabbits, etc.

- (b) *Nature of the invention* - The nature of the invention is drawn to compounds for use in controlling pests.
- (c) *Amount of direction provided by the inventor and Existence of working examples* - Applicant has provided guidance as to the particular type of pests for which the instant compounds have controlling effects. On page 107 of the specification, Applicant states that:

Pests against which the present compound has controlling effect include harmful arthropods such as insects and mites, and harmful nematodes. More specifically, examples thereof are listed below.

Applicant then continues by listing various types of species that fall within the class of pests taught by Applicant.

Applicant continues on pages 116-118, by describing particular scenarios in which the instant pesticides may be used. For instance, the instant pesticides can be applied to plants to protect them from pests (page 117, lines 10-11) to soil and seedbeds to protect them from pests living in the soil (page 117, lines 9-15), to animals, such as cows, horse, pigs, rat and mice, by tablet, injection, spraying or spot-on treatment (page 118, lines 6-23). Each of these applications results in the application of the instant compounds to other subjects that can fall with the broad definition of "pests". Applicant's claims are drawn to controlling any type of pest, but the guidance in the specification literally leads of ordinary skill to control pests from other pests. There is no guidance in identifying which pests will actually be controlled under which circumstances when using the instant compounds. For instance, in one method of the invention, the instant compounds can be used to protect mice from insect pests while in another the instant compounds are to be used to control mice. There is no guidance in how to control certain pests in one circumstance but not another using the instant compounds.

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On pages 247-252, Applicant has provided working examples of controlling arthropod or nematode pests; however, the working examples do not allow one of ordinary skill in the art to extrapolate the limited working examples to the ability to controlling any or all types of pests. See section (d), below.

- (d) *Quantity of experimentation needed to make or use the invention based on the content of the disclosure* - Predicting whether a recited compound is in fact one that produces a desired effect on a pest is extremely unpredictable absent guidance with respect to what type of pests are likely to be controlled with said compound. The instant direction and guidance provided by Applicant would lead one of ordinary skill in the art to the ability to control arthropod or nematode pests with a reasonable level of predictability and without undue experimentation since Applicant teaches that several species within these categories were successfully controlled. U.S. Patent No. 6,663,860 by Tvedten teaches that:

Most pesticides are generally insect or arachnid nervous system toxicants, inhibiting or overpotentiating synapse-synapse and/or neuro-muscular junction transmission, many acting specifically as acetylcholinesterase inhibitors.

Accordingly, one of ordinary skill in the art could reasonably extrapolate the instant guidance and working examples to the ability to control other arthropod or nematode pests since the other species are likely to have a similar biological response to the instant compounds. There is no guidance or working example in the instant case to demonstrate that the instant compounds can be used to treat any type of pest. As noted in section (a), the scope of "pests" is exceedingly broad and there is little predictability in determining how one species of a pest, for instance a deer, may respond to a chemical based on how another pest, for instance an insect, responded to that same chemical since they are quite different biologically. Instead, one of ordinary skill in the art must engage in undue experimentation to determine which types of pests can be controlled using the instant compounds without any assurance of success.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. {*In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)}.

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The determination that *undue experimentation* would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. (*In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404). These factual considerations are discussed comprehensively in MPEP § 2164.08 (scope or breadth of the claims), § 2164.05(a) (nature of the invention and state of the prior art), § 2164.05(b) (level of one of ordinary skill), § 2164.03 (level of predictability in the art and amount of direction provided by the inventor), § 2164.02 (the existence of working examples) and § 2164.06 (quantity of experimentation needed to make or use the invention based on the content of the disclosure).

Based on a preponderance of the evidence presented herein, the conclusion that applicant is insufficiently enabled for a method for controlling any type of pest is clearly justified.

Claim Rejections - 35 USC § 112 - 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 provides for the use of the compound of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

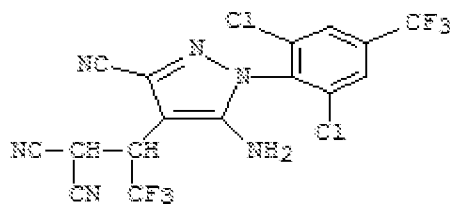
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 16, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent Document No. JP 11171702.

Determining the scope and contents of the prior art. (See MPEP § 2141.01)

JP 11171702 teaches compounds useful in controlling pests. Furthermore, the prior art reference specifically teaches the following species as a preferred embodiment on page 39 (Compound No. 1-139):

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Ascertainment of the differences between the prior art and the claims. (See MPEP § 2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art. Furthermore, the difference between a species taught by the prior art and one instantly claimed is that of hydrogen versus methyl.

Finding of prima facie obviousness --- rationale and motivation (See MPEP § 2141.02)

"Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." *In re Deuel* 34 USPQ2d 1210 at 1214. Furthermore MPEP 2144.09 (II) states: "Compounds which are [...] homologs (...) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977)."

The issue of patentability over the replacement of alkyl groups for hydrogen has arisen many times. For instance, the replacement of a methylene group with a dialkyl-substituted methylene group was determined to be *prima facie* obvious on the ground that "one skilled in the art would have been, *prima facie*, motivated to make the claimed compounds in the expectation that they, too, would possess antimicrobial activity." (*In re Wood* 199 USPQ 137) See also *In re Doebel* 174 USPQ 158 (where replacement of methyl for hydrogen

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on an amino nitrogen was considered *prima facie* obvious - at page 159); *In re Druey* 138 USPQ 39 (where replacement of methyl for hydrogen on a known compound was considered *prima facie* obvious based on the homologous and close structural relationship to the known compound - at page 41); *In re Lohr* 137 USPQ 548 (where the replacement of a methyl group for a hydrogen on two positions of a tetrahydropyran ring on a known compound was not considered a patentable modification given the close structural relationship to the known compounds - at page 550); *Ex parte Bluestone* 135 USPQ 199 (where fungicidal compounds differing by hydrogen versus methyl on the nitrogen of a thiazolidine-2-thione ring were considered homologs and were not found to be patentable over each other without a showing of unexpected results - at page 200); *Ex parte Weston* 121 USPQ 429 (where the replacement of methyl for hydrogen on the nitrogen of a piperazine ring was not found to be a patentable modification); *Ex parte Fauque* 121 USPQ 425 (where di(methyl-furyl)-methane was considered a higher homolog of difuryl-methane and unpatentable without a showing of unexpected results - at page 426).

The motivation to make a substitution of an alkyl group for hydrogen stems from the fact that a person having ordinary skill in the art would expect that the compounds could be prepared by the same method as taught by the prior art and have the same utility as the compounds taught by the prior art. In the interest of generating additional compounds that have the same utility as the compounds taught by the prior, a person having ordinary skill in the art would seek to make additional compounds that are most closely related to compounds specifically taught by the prior art that have already been demonstrated to have the desired utility. As discussed *supra*, the replacement of hydrogen for an alkyl group falls under the well-established doctrine of homology, which assumes that homologous compounds are likely to

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have similar properties. Therefore, the instantly claimed compounds, which differ by hydrogen/alkyl, over compounds of prior art are unpatentable absent a showing of unexpected results. MPEP 2144.09 (VII) states "A prima facie case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)." In the instant case, Applicant has not established unexpected properties between the instantly claimed compounds are the closest prior art homologs. In the instant case, a person having ordinary skill in the art at the time the invention was made would have been motivated to synthesize the instantly claimed homologs with the reasonable expectation that they would have the same utility as the closest structurally related compounds taught by the prior and with the motivation of obtaining additional useful compounds.

Allowable Subject Matter

Claims 2, 4-15 and 19-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and amended to correct for the claim objections noted above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew P. Coughlin whose telephone number is (571)270-1311. The examiner can normally be reached on Monday through Thursday from 7:30 am - 5:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew P. Coughlin/ Examiner, Art Unit 1626	/Rebecca L Anderson/ Primary Examiner, Art Unit 1626
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